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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number

10/512,025

Filing Date

October 4, 2005

First Named Inventor

Vishwanath R. Lingappa

Group Art Unit

1642

Examiner Name

Minh Tam B. Davis

Total Number of Pages in This Submission

Attorney Docket Number

305JP-010210US

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment / Response
- ☐ Amendment and Request for Reconsideration
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☒ Receipt Acknowledgement Postcard
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53

- ☐ PTO-1449 Form
- ☐ Cited References
- ☐ Copy of PCT Search Report
- ☐ Copy of EP Search Report
- ☐ CD, Number of CD(s) _____
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Small Entity Statement
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- ☐ Interview Summary
- ☐ Request for Continued Examination (RCE)
- ☐ Request for Corrected Filing receipt
- ☐ Copy of Filing Receipt - marked up
- ☐ Status Letter
- ☒ Additional Enclosure(s) (please identify below):
 - Request for Notice of Abandonment Cover Letter;
 - Copy of Office communication

Authorization to Charge Deposit Account

Please charge Deposit Account No. 50-0893 for any additional fees associated with this paper or during the pendency of this application, including any extensions of time for consideration of the documents enclosed.

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name

Stacy Landry, Reg. No. 42,779, Quine Intellectual Property Law Group, P.C.

Signature

Stacy Landry

Date

September 5, 2008

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below

Typed or printed name

Kimberly Cheung

Signature

Kimberly Cheung

Date

September 5, 2008



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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

By: _____

Kimberly Cheung

Appl. No. : 10/512,025
Applicant : Vishwanath R. Lingappa et al.
Filed : October 4, 2005
TC/A.U. : 1642
Examiner : Minh Tam B. Davis
Docket No. : 305JP-010210US
Customer No. : 22798
Client Ref No.: SF-2002-72-2US

Confirmation No. 6909

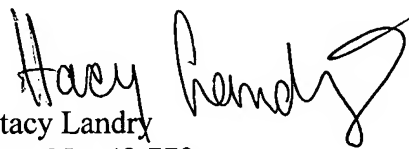
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We received the enclosed communication dated August 18, 2008. We note that while the cover page lists the information for the above-referenced application (USSN 10/512,025), the attached communication refers to USSN 11/383,309, which our firm is not handling. We have checked private PAIR, and it appears that we should have received a Notice of Abandonment for the above-referenced application, rather than a final Office Action. We respectfully request a copy of the Notice of Abandonment for the above-referenced application.

QUINE INTELLECTUAL
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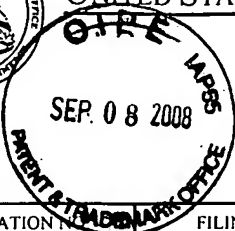
Respectfully submitted,


Stacy Landry
Reg. No. 42,779

Enclosure: Copy of Office communication dated August 18, 2008



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,025	10/04/2005	Vishwanath R. Lingappa	UCSF.004.01US	6909

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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08/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Abandoned



COPY

Office Action Summary	Application No. 11/383,309	Applicant(s) THORNE, KEVIN J.	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/9/08.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
4a) Of the above claim(s) 13-24 and 31-50 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-12 and 25-30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/08</u> | 6) <input type="checkbox"/> Other: _____ |

COPY

Application/Control Number: 11/383,309
Art Unit: 1655

Page 2

DETAILED ACTION

Claims 1-50 remain pending in the application.

Applicant's election without traverse of claims 1-12 and 25-30 as well as Applicant's election without travers of the species of calcium hydrogen phosphate dihydrate in the reply filed on 1/22/08 was acknowledged in the non-final Office action mailed on 3/31/08. It is reminded that claims 1-12 and 25-30 read on the elected species and claims 13-24 and 31-50 remain withdrawn from examination on the merits, as these claims are directed toward a non-elected invention.

Claims 1-12 and 25-30 were examined on their merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 11/383,309
Art Unit: 1655

Page 3

Claims 1, 3-6, 25 and 27-30 remain rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. : INVESTIGATION INTO THE FORMATION AND MECHANICAL PROPERTIES OF A BIOACTIVE MATERIAL BASED ON COLLAGEN AND CALCIUM PHOSPHATE; Journal of materials Science Materials in Medicine 4, (1993) 107-110; cited herein as 'Clarke et al. (1993)' as keenly addressed in the previous Office action.

Applicant has amended claim 1 to read:

Claim 1. (Currently amended) A bone growth composition, comprising:
a bone growth protein having a first bioactivity at a neutral or basic pH; and
an acidic substrate;
wherein the bone growth protein has a second bioactivity greater than the first bioactivity
when combined with the acidic substrate.

(underlined text appears in the claim submitted on 5/6/2008 as added text)

Applicant argues that Clarke et al. is silent with regard to the newly recited limitation 'at a neutral or basic pH' and therefore cannot anticipate the claimed invention. Specifically, Applicant argues that "...the difference between the first bioactivity and the second bioactiity is solely the difference between the activity in the presence of a non-acidic substrate and the presence f a comparable amount of an acidic substrate...Clarke presence no evidence that Ser P has a higher activity at an acidic pH than at a neutral or basic pH... (pp. 9-10 Remarks).

However, it is decided that although Clark et al. performed their study in an acidic pH (a pH of 5.5), that claim 1 and claims dependant therefrom do not require a neutral or basic pH; on the contrary, the claims only require that the composition has a second bioactivity greater than the first bioactivity. This is an inherent property of the bone composition disclosed by Clarke et al. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant has neither added or substracted any limitations to the claimed composition by the addition of 'at a neutral or basic pH.' The burden shifts to the Applicant to show that the product of the prior art as disclosed by Clarke et al. would not have the effect of the product as recited by the Instant claims. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113). In the Instant case, any discovery made that indicates that the composition of the cliams (and hence of Clarke et al.) which indicates that bone protein and an acidic substrate will perform (i.e., produce bone or have some other bioactivity) in basic or neutral pH does not change the fact that the bone composition of the claims is the same composition as that already well-known in the prior art. Accordingly, in order to distinguish the claimed invnetion from the prior art,

the claimed composition must be limited to specific embodiments which were not taught or suggested by the prior art.

Claims 1-12 and 25-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (1993) in view of Constantz (US 5,455,231) in view of Piez et al. (US 4,795,467) for the reasons keenly established in the previous Office action.

Applicant's arguments concerning this rejection rely primarily on the arguments set forth in traversal of the rejection made under 35 USC 102(b), that is, that none of the references taught that the composition had a greater bioactivity when combined with an acidic substrate, and therefore, contends that the combined references do not render the claimed invention obvious (pp. 10-11, Remarks). However, these arguments are not found convincing for the same reasons set forth *supra* with regard to Applicant's arguments in traversal of the rejection made under 35 USC 102(b); those reasons being that the claims do not require a pH, only that the bone protein, when combined with an acidic substrate, has a greater bioactivity than the bone protein itself. The bone protein has no bioactivity if it is left alone in a petri dish for example; however, bone protein, when combined with an acidic substrate such as an acidic bone substrate under suitable conditions for producing bone, produces bone. Applicant's statement 'at a neutral or basic pH' again does not impart any limitations to the claimed invention and

hence, it is deemed that the claims are made obvious by the reasons already set forth on the record.

Applicant argues that Constatz completely fails to teach any materials having an acidic pH (p. 11, Remarks). This argument is respectfully found incorrect; brushite, also known as calcium hydrogen phosphate dihydrate' is an acidic bone material. The same bone material as Instantly claimed.

Applicant argues that Piez teaches 'there have been numerous attempts to use combinations of calcium phosphate mineral components and collagen in various forms of bone defect repair with mixed success', hence, Applicant contends that Piez does not provide motivation for varying the amounts of constituents as Instantly claimed as decided by the Examiner (pp. 10-11, Remarks). Applicant's contentions are not found persuasive. It would be expected that some combinations of calcium phosphate minerals and collagen would fail to produce bone; this is the essence of routine scientific experimentation. The Piez reference is merely cited to indicate that the claimed amounts of ingredients are well-within the realm of routine experimentation and the failures of some bone preparations (which would of course, be expected) does not negate the fact that Clarke et al. already taught that the combination of brushite (the claimed, and specific species of calcium phosphate compound elected by Applicant) and SerP protein (a bone protein) as well as collagen were known to be used in concert to successfully produce bone material. Hence, the ordinary artisan, having the Clarke et

al. reference in front of him or her, in addition to the secondary references of Constanz and Piez would have been motivated to routinely adjust the amounts of ingredients or to vary the type of bone protein in order to optimize bone formation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

Applicant's arguments with regard to a 112 second rejection are correct, the examiner did not formally set forth a rejection under 35 USC 112 second rejection in the previous Office action as upon further consideration (upon instituting the Office action) it was decided that while the term 'bioactivity' is quite broad, it is not indefinite. One of ordinary skill in the art could test for any type of bioactivity of a bone protein and then test again in combination with an acidic substrate to determine if the second bioactivity is greater. Further, as noted *supra*, the first and second bioactivities are deemed inherent properties of the mixture as disclosed by Clarke et al. in that they do not impart any physical characteristics to the claimed invention in order to actually distinguish the claimed invention from that of the prior art.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

COPY

Application/Control Number: 11/383,309
Art Unit: 1655

Page 9

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655